DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0512]

Guidance for Industry and Food and Drug Administration Staff; User Fees and Refunds for Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''User Fees and Refunds for Premarket Approval Applications.'' This guidance outlines the types of premarket approval applications (PMAs), including supplements and other submissions, that are subject to user fees as well as those that do not have an associated fee. The guidance also identifies industry and FDA actions on these submissions that may result in a partial refund of the fee. The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''User Fees and Refunds for Premarket Approval Applications'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your

request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding device issues: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

Regarding biologics issues: Sayah Nedjar, Center for Biologics Evaluation and Research (HFM–380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), amends the Federal Food, Drug, and Cosmetic Act to allow FDA to collect user fees for certain premarket reviews. The new law also permits partial refunds under certain circumstances, such as in the case of a non-filing decision for a PMA. In other cases, the statute permits a refund but stipulates that it is to be in an amount determined by the level of effort expended by the agency during its review of the application. The guidance outlines the user fees due with certain PMAs, the refunds set by statute, and FDA's plan for determining the amount of the fee to be refunded when the exact amount is not prescribed by the new law.

FDA is making this guidance document immediately available because prior public participation was not feasible. MDUFMA's user fee provisions were effective immediately, and it is essential for the agency to provide guidance to its stakeholders on the user fee program as quickly as possible. Although it was not feasible to obtain comments before issuing the guidance, in accordance with this agency's GGP procedures, FDA will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive a copy of ''User Fees and Refunds for Premarket Approval Applications'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1224) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints,

information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the user fee forms (OMB control number 0910–0511), which expires on August 31, 2006, and the regulations governing administrative practices and procedures (21 CFR part 10, OMB control number 0910–0192).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with

the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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